

Message

From: Thayer, Kris [thayer.kris@epa.gov]
Sent: 11/22/2017 3:37:34 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Bussard, David [Bussard.David@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

My calendar is up to date, I'm on leave Dec 20-Jan 4 but could do Dec 21 or 22 (not 20th since I'll be in the air)

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Wednesday, November 22, 2017 10:33 AM
To: Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Joke Herremans <joke.herremans@rivm.nl>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

It is our turn to apologize for a delay.

Yes, we would be very interested to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. As I have already informed you, we are currently in the process of updating our national air limit for this chemical and we would like to use the data as presented in the 2010 draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data as presented in this Draft.

We would appreciate the opportunity to discuss the current status of the IRIS Toxicological Review of Formaldehyde.

We are also interested if there is any possibility to use the data (especially derived inhalation cancer unit risk for NPC (Nasopharyngeal Cancer)), without referring as to an official EPA position, but rather a scientific approach.

We have noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

We also would like to know, how will US-EPA react to the comments of NAS (especially their comments on the calculation of the unit risks)? Moreover, will the unit risk calculation change in the near future?

Here are several dates we would like to propose:

13th, 20th, 21st or 22nd of December 2017, 9 – 10 am EST (15:00 – 16:00 our time), or

17th, 18th, 24th or 25th of January 2018, 9 – 10 am EST (15:00 – 16:00 our time).

We hope to hear from you soon.

Kind regards

Lidka

Lidka Maslankiewicz
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From: "Glenn, Barbara" <Glenn.Barbara@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>,
Cc: "Bussard, David" <Bussard.David@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, Els Smit <els.smit@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Thayer, Kris" <thayer.kris@epa.gov>, Theo Vermeire <theo.vermeire@rivm.nl>
Date: 10/10/2017 04:48 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Lidka,

We would like to schedule a time to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. It would be great to explore what might be possible. I have some proposed dates and times for you to select from. Will this be possible for you?

Oct. 30 9 – 10 am EST

Nov 1 9 – 10 am EST

Nov 7 9 – 10 am EST

Thank you very much for your patience with our process and timing. Regards, Barbara and Andrew

From: Lidka Maslankiewicz [<mailto:lidka.maslankiewicz@rivm.nl>]
Sent: Friday, September 22, 2017 4:54 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Joke Herremans <joke.herremans@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: *"It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."*

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of

formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

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From: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Els Smit <els.smit@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Joke Herremans" <joke.herremans@rivm.nl>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard.David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>
Date: 09/08/2017 05:21 PM
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment . We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations,
Andrew and Barbara

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Tuesday, August 29, 2017 7:59 AM
To: Kraft, Andrew
Cc: Els Smit; Paul Janssen; Joke Herremans
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,

My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.

We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response" (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...

cfpub.epa.gov

EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

Kind regards

Lidka

Lidka Maslankiewicz

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